(m) A claim for benefits under § 416.351 based on alleged misinformation; and

* * * * *

Dated: March 7, 1995.

Neil J. Stillman,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 95–6502 Filed 3–15–95; 8:45 am]

BILLING CODE 4190–29–M

Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address for a new animal drug application (NADA) from Zoecon Industries, Inc., to Sandoz Agro, Inc.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Due to a merger with Zoecon Industries, Inc., 12200 Denton Dr., Dallas, TX 75234, and Sandoz Agro, Inc., 1300 East Touhy Ave., Des Plaines, IL 60018, the firms have requested that FDA publish a notice of a change of sponsor name and address for their new animal drug application NADA 98–895, Starbar GX–118 (N-(mercaptomethyl) phthalimide S-(O,O dimethylphosphorodithioate) emulsifiable liquid). Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name and address. The drug labeler code ''011536'' for Zoecon Industries, Inc., is being retained for the new sponsor.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Zoecon Industries, Inc.,'' and alphabetically adding a new entry for ''Sandoz Agro, Inc.,'' and in the table in paragraph (c)(2) in the entry for ''011536'' by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	*
Sandoz Agro, Inc., 1300 East Touhy Ave., Des Plaines, IL 60018	011536
* * * *	*

(2) * * *

Drug labeler code	Firm name and address
*	* * * *
011536	Sandoz Agro, Inc., 1300 East Touhy Ave., Des Plaines, IL 60018
*	* * * *

Dated: March 8, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–6528 Filed 3–15–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by The Upjohn Co. The NADA provides for the use of lincomycin hydrochloride soluble powder to make medicated swine and broiler chicken drinking water. The supplement provides for use of a packet containing the equivalent of 32 grams (g) of lincomycin in addition to the currently approved packet containing the equivalent of 16 g of lincomycin.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, filed a supplement to NADA 111–636 for Lincomix (lincomycin hydrochloride) soluble powder. The supplemental NADA provides for the use of an 80-g packet containing the equivalent of 32 g of lincomycin in addition to the approved 40-g packet containing the equivalent of 16 g of lincomycin. Both packets are used to make a swine drinking water containing 250 milligrams (mg) of lincomycin per gallon used for the treatment of swine dysentery and broiler chicken drinking water containing 64 mg of lincomycin per gallon for the control of necrotic enteritis.

This supplemental NADA is approved as of February 9, 1995, and the regulations in § 520.1263c(a) (21 CFR 520.126c(a)) are amended to reflect the approval.

This is a manufacturing supplement to an approved NADA. The approval does not require a summary of safety, effectiveness data, or information. Therefore, a freedom of information summary as provided in part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)) is not required.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals does not qualify for marketing exclusivity because the supplemental application does not contain new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1263c is amended by revising paragraph (a) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin.

* * * * *

Dated: March 8, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–6531 Filed 3–15–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Sanofi Animal Health, Inc. The ANADA provides for the use of a generic neomycin sulfate soluble powder administered orally in drinking water or in milk for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Sanofi Animal Health, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed ANADA 200–050, which provides for the oral use of neomycin sulfate soluble powder in drinking water or milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin sulfate.

Approval of ANADA 200–050 is as a generic copy of The Upjohn's approved NADA 11–315 for Neomix® 325 soluble powder. The ANADA is approved as of February 15, 1995, and the regulations are amended by revising § 520.1484(b) (21 CFR 520.1484(b)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1484 is amended by revising paragraph (b) to read as follows:

§ 520.1484 Neomycin sulfate soluble powder.

* * * * *

(b) *Sponsors.* See Nos. 000009, 000069, 050604, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: March 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–6530 Filed 3–15–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of oxytetracycline injection in cattle and swine for the treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: March 16, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–123 which provides for use of oxytetracycline injection as follows: (1) Intramuscular or intravenous use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline; (2) intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*; and (3) intramuscular use in sows for control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli.*

Phoenix Scientific's ANADA 200–123 for oxytetracycline injection (Maxim 200) is approved as a generic copy of Pfizer's NADA 113–232 for oxytetracycline injection (Liquamycin®